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Glenmark USA receives tentative ANDA approval for Dronedarone

06 January 2016 | News | By BioSpectrum Bureau

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'Tentative approval' means that FDA has concluded that a drug product has met all required quality, safety and efficacy standards, but is not eligible for marketing in the US because of existing patent protections or exclusivities.

Glenmark believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for Dronedarone Tablets and expects to be eligible for 180 days of generic drug exclusivity upon final FDA approval.

Glenmark remains involved in a patent litigation in the US District Court for the District of Delaware, wherein Sanofi and Sanofi-Aventis US has asserted its patents.

According to IMS Health sales data for the 12 month period ending November 2015, the Multaq market achieved annual sales of approximately $425.7 million.

Glenmark's current portfolio consists of 104 products authorized for distribution in the US marketplace and 62 ANDA's pending approval with the USFDA.

In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.